

EXHIBIT A

--- F.3d ---, 2009 WL 3448282 (C.A.9 (Ariz.)), 09 Cal. Daily Op. Serv. 13,106
(Cite as: 2009 WL 3448282 (C.A.9 (Ariz.)))

H

United States Court of Appeals,
Ninth Circuit.
James SIRACUSANO, Individually and on behalf of
all others similarly situated, Plaintiff-Appellant,
Neca-Ibew Pension Fund, Claimant-Appellant,
v.
MATRIX INITIATIVES, INC.; Carl J. Johnson;
William J. Hemelt, Defendants-Appellees.
No. 06-15677.

Argued and Submitted June 9, 2009.
Filed Oct. 28, 2009.

Background: Investors brought class action against pharmaceutical company and three of its executives, alleging that defendants violated federal securities laws by failing to disclose material information regarding one of the company's products. The United States District Court for the District of Arizona, [Mary H. Murguia](#), P. J., 2005 WL 3970117, granted in part and denied in part defendants' motion to strike, and granted defendants' motion to dismiss. Investors appealed.

Holdings: The Court of Appeals, [Tashima](#), Circuit Judge, held that:

(1) investors adequately pled materiality under the Private Securities Litigation Reform Act (PSLRA), and

(2) investors pled scienter with the requisite particularity under the PSLRA.

Reversed and remanded.

West Headnotes

[1] Federal Courts 170B

170B Federal Courts

A district court's dismissal for failure to state a claim is reviewed de novo.

[2] Securities Regulation 349B

349B Securities Regulation

Section 10(b), in combination with Rule 10b-5, prohibits any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of

any security. Securities Exchange Act of 1934, § 10(b), [15 U.S.C.A. § 78j\(b\)](#); [17 C.F.R. § 240.10b-5\(c\)](#).

[3] Securities Regulation 349B

349B Securities Regulation

In order adequately to allege a violation of Rule 10b-5, a plaintiff must allege (1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss. [17 C.F.R. § 240.10b-5\(c\)](#).

[4] Securities Regulation 349B

349B Securities Regulation

Investors bringing securities fraud class action against pharmaceutical company and three of its executives, alleging defendants failed to disclose information regarding the possible link between one of the company's products and anosmia, sufficiently pled materiality under the Private Securities Litigation Reform Act (PSLRA), by alleging the company received some customer complaints about the product in question and anosmia, that the company's vice president called a doctor because one of the doctor's patients had complained to the company about the product in question and anosmia, that a university researcher presented findings about 10 or 11 patients who suffered anosmia following use of the company's product, that the company stopped the researcher from using the company's and the product's names in the presentation, and that lawsuits had been brought against the company alleging that the company's product caused anosmia. Private Securities Litigation Reform Act of 1995, § 101(b)(1), [15 U.S.C.A. § 78u-4\(b\)\(1\)](#).

[5] Securities Regulation 349B

349B Securities Regulation

An omitted fact is "material" under Rule 10b-5 if there is a substantial likelihood that a reasonable shareholder would consider it important in deciding how to vote. [17 C.F.R. § 240.10b-5\(c\)](#).

[6] Securities Regulation 349B

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Questions of materiality under Rule **10b-5** involve assessments peculiarly within the province of the trier of fact; thus, the ultimate issue of materiality is appropriately resolved as a matter of law only where the omissions are so obviously important to an investor, that reasonable minds cannot differ on the question of materiality. [17 C.F.R. § 240.10b-5\(c\)](#).

[7] Securities Regulation 349B

[349B](#) Securities Regulation

Courts should engage in a fact-specific inquiry in assessing materiality under Rule **10b-5**; thus, determining materiality in securities fraud cases should ordinarily be left to the trier of fact. [17 C.F.R. § 240.10b-5\(c\)](#).

[8] Securities Regulation 349B

[349B](#) Securities Regulation

Investors bringing securities fraud class action against pharmaceutical company and three of its executives, alleging defendants failed to disclose information regarding possible link between one of the company's products and anosmia, pled scienter with requisite particularity under the Private Securities Litigation Reform Act (PSLRA), by alleging that company received customer complaints about the product in question and anosmia from 1999 to 2002, that in September 2003, company knew a researcher and his colleagues were presenting findings about 10 or 11 patients who developed anosmia after using the product and did not allow the researcher to use the company's or the product's name in the presentation, that in October 2003, company touted the potential for growth and profitability of product in a press release and earnings conference call, and that in November 2003, company filed a Form 10-Q, but did not disclose lawsuit filed in October 2003. Private Securities Litigation Reform Act of 1995, § 101(b)(2), [15 U.S.C.A. § 78u-4\(b\)\(2\)](#).

[9] Securities Regulation 349B

[349B](#) Securities Regulation

To plead scienter under the Private Securities Litigation Reform Act (PSLRA), a plaintiff must allege that the defendant had an intention to deceive, manipulate, or defraud. Private Securities Litigation Reform Act of 1995, § 101(b)(2), [15 U.S.C.A. § 78u-4\(b\)\(2\)](#).

[10] Securities Regulation 349B

[349B](#) Securities Regulation

In determining whether the pled facts giving rise to a strong inference of scienter under the Private Securities Litigation Reform Act (PSLRA), the court must take into account plausible opposing inferences; the complaint will survive a motion to dismiss only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged. Private Securities Litigation Reform Act of 1995, § 101(b)(2), [15 U.S.C.A. § 78u-4\(b\)\(2\)](#).

[11] Securities Regulation 349B

[349B](#) Securities Regulation

To establish scienter under the Private Securities Litigation Reform Act (PSLRA), a complaint must allege that the defendants made false or misleading statements either intentionally or with deliberate recklessness. Private Securities Litigation Reform Act of 1995, § 101(b)(2), [15 U.S.C.A. § 78u-4\(b\)\(2\)](#).

[12] Securities Regulation 349B

[349B](#) Securities Regulation

In determining whether a plaintiff adequately pled scienter under the Private Securities Litigation Reform Act (PSLRA), a court must first determine whether any of the plaintiff's allegations, standing alone, are sufficient to create a strong inference of scienter; if not, the court is to conduct a holistic review of the same allegations to determine whether the insufficient allegations combine to create a strong inference of intentional conduct or deliberate recklessness. Private Securities Litigation Reform Act of 1995, § 101(b)(2), [15 U.S.C.A. § 78u-4\(b\)\(2\)](#).

[13] Securities Regulation 349B

[349B](#) Securities Regulation

"Recklessness," for purposes of establishing scienter under the Private Securities Litigation Reform Act (PSLRA), is defined as a highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either

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known to the defendant or is so obvious that the actor must have been aware of it. Private Securities Litigation Reform Act of 1995, § 101(b)(2), [15 U.S.C.A. § 78u-4\(b\)\(2\)](#).

[14] Securities Regulation 349B

[349B](#) Securities Regulation

Withholding reports of adverse effects of and lawsuits concerning the product responsible for the company's remarkable sales increase is an extreme departure from the standards of ordinary care and presents a danger of misleading buyers or sellers, for purposes of establishing scienter under the Private Securities Litigation Reform Act (PSLRA). Private Securities Litigation Reform Act of 1995, § 101(b)(2), [15 U.S.C.A. § 78u-4\(b\)\(2\)](#).

[Joseph D. Daley](#), Coughlin Stoia Geller Rudman & Robbins LLP, San Diego, CA, for the plaintiff-appellant.

[Michael G. Yoder](#), O'Melveny & Myers LLP, Newport Beach, CA, for the defendants-appellees.

Appeal from the United States District Court for the District of Arizona, [Mary H. Murguia](#), District Judge, Presiding. D.C. Nos. CV 04-0886 MHM, CV 04-1012 MHM.

Before [MARY M. SCHROEDER](#), [A. WALLACE TASHIMA](#) and [CARLOS T. BEA](#), Circuit Judges.

OPINION

[TASHIMA](#), Circuit Judge:

*1 Matrixx Initiatives, Inc. ("Matrixx") is a pharmaceutical company that sells cold products through its wholly-owned subsidiary, Zicam, LLC. One of its main products is Zicam Cold Remedy, which comes in several different forms. ^{FN1} Plaintiffs-Appellants are lead plaintiff, NECA-IBEW Pension Fund, and named plaintiff, James Siracusano, in a class action brought against Matrixx and three Matrixx executives (collectively "Appellees") under the Private Securities Litigation Reform Act of 1995 ("PSLRA"). Appellants alleged that Appellees violated the Securities Exchange Act of 1934 by failing to disclose material information regarding Zicam Cold Remedy—specifically, that Zicam causes a condition called

anosmia, which is a loss of the sense of smell, in its users. The district court granted in part and denied in part Appellees' motion to strike portions of the complaint and granted Appellees' motion to dismiss the complaint and the action. We have jurisdiction pursuant to [28 U.S.C. § 1291](#). We reverse and remand for further proceedings.

BACKGROUND ^{FN2}

On April 27, 2004, Appellants filed a class action against Matrixx and three individual defendants—Carl Johnson, Matrixx's Chief Executive Officer, President and a director; William Hemelt, Matrixx's Chief Financial Officer and Executive Vice President; and Timothy Clarot, Matrixx's Vice President and Director of Research and Development—on behalf of investors who purchased Matrixx securities during the class period, October 22, 2003, to February 6, 2004. Zicam Cold Remedy accounted for approximately 70 percent of Zicam's sales during the class period. Zicam Cold Remedy's active ingredient is zinc gluconate and can be applied as a nasal spray or a gel. Appellants alleged that Appellees were aware that numerous users of Zicam had developed anosmia, but that they failed to disclose the risk and instead issued false and misleading statements regarding Zicam.

I. Allegations of Adverse Information Regarding Zicam

In December 1999, Dr. Alan Hirsch, the Neurological Director of the Smell & Taste Treatment and Research Foundation, Ltd., "called Matrixx's customer service line to inquire into the amount of zinc contained in Zicam nasal gel." CAC ¶ 25. Hirsch spoke with a Mr. Landau and explained that at least one of Hirsch's patients had developed anosmia after using Zicam. Hirsch stated that other studies had indicated potential problems with "intranasal application of zinc," and offered to conduct a clinical study on the issue. Mr. Landau declined his offer.

In September 2002, Clarot, Vice President of Research and Development, called Miriam Linschoten, Ph.D., of the University of Colorado Health Sciences Center. Clarot contacted Linschoten because a patient Linschoten had treated for loss of smell following use of Zicam also had complained to Matrixx. Linschoten expressed concern that Zicam, an over-the-counter product, contained no warning that it could cause a

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loss of smell. Clarot told Linschoten that Matrixx had received similar complaints from other customers as early as 1999. Linschoten asked whether Matrixx had performed any studies, told Clarot about existing studies linking zinc sulfate to the loss of smell, and offered to send Clarot information regarding those studies. Clarot replied that Matrixx had not done any studies but that “it had hired a consultant to review the product.” CAC ¶ 26.

*2 On September 20, 2002, Linschoten sent an email to Clarot including abstracts on the link between zinc sulfate and the loss of smell. Clarot called Linschoten to ask if she would participate in animal studies to be conducted by Matrixx, but Linschoten declined because she focused on human, not animal, research.

Linschoten, Dr. Bruce Jafek of the University of Colorado School of Medicine, and another colleague planned to submit their findings regarding ten patients who had developed anosmia following Zicam use in a presentation to the American Rhinologic Society on September 20, 2003. On September 12, 2003, “Matrixx sent a letter to Jafek stating that he did not have permission to use Matrixx’s name or the names of its products” in the presentation. CAC ¶ 29. Jafek asked for permission to use the Zicam name, but Matrixx refused. The presentation to the American Rhinologic Society accordingly was made without naming Zicam. “Jafek’s findings regarding Zicam were ultimately disclosed to the public on February 6, 2004 on *Good Morning America*.” *Id.*

“As of April of 2004, Dr. Jafek had evaluated over 100 cases of anosmia following Zicam use.” CAC ¶ 30. Linschoten had treated approximately 65 such patients, all of whom complained of “an ‘immediate, severe burning’ immediately following use of Zicam nasal gel, followed by a loss of smell.” None of the patients had fully recovered. *Id.* Jafek and Hirsch “have observed that the Zicam nasal spray does reach the upper area of the nasal cavity where smell reception occurs.”

II. Allegations of Misleading Statements

On October 22, 2003, Matrixx issued a press release announcing that its net sales for the third quarter of 2003 had increased by 163% over the third quarter of 2002. Johnson was quoted in the press release as follows:

The Zicam brand is poised for growth in the upcoming cough and cold season with improved retail exposure by virtue of three [new] unique oral delivery forms of our Zicam Cold Remedy product, the resumption of our television advertising campaigns in recent weeks and the momentum from last year’s successful season. Additionally, our retail partners have come to rely on the Zicam brand not only as an efficacious product for their customers, but also for the profitability that Zicam branded products produce for their respective bottom-lines.

Matrixx 10/22/2003 press release. Appellants alleged that these statements were materially false and misleading because they failed to disclose Appellees’ awareness of the material health risk that Zicam posed to consumers.

On October 23, 2003, Appellees held an earnings conference call, at which Johnson expressed his “enthusiasm for the most recently completed quarter” and his “optimis[m] about the future.” 10/23/03 Tr. at 1. Johnson explained that

we have very strong momentum going into the upcoming cough and cold season. In addition, what lies behind these results is a unique product in the Zicam product line, a product that offers a unique benefit, the ability for consumers to actually reduce the duration and severity of the common cold, not just mask the symptoms, and tremendous support that we are receiving from our retail customers.

*3 *Id.* at 2. Johnson further expressed the expectation for the year that “our revenues will be up in excess of 50% and that earnings per share for the full year will be in the 25-30 range.” *Id.* at 5. Hemelt stated that the growth “was driven by increased sales of all 10 of our Zicam products,” explaining that approximately one-third of the increase in sales was due to “three new Zicam oral cold remedy products,” and that the remainder of the increase “was due to increased sales of our other seven Zicam products.” *Id.* at 4. Johnson and Hemelt then answered questions.

At one point, they were asked to “make any comment on the litigation MTXX or its officers are involved in, or whether or not there is any SEC [Securities and Exchange Commission] investigation.” *Id.* at 17. They replied that “[t]he officers of this company are

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not involved in any litigation,” and that they were not aware of any SEC investigation.^{FN3} *Id.* at 17-18. Johnson concluded by reiterating “the optimism we have for the future.” *Id.* at 32. There was no mention of the anosmia issue.

On November 12, 2003, Matrixx filed its Form 10-Q report for the third quarter of 2003 with the SEC. The section of the Form 10-Q that Appellants alleged was false and misleading was this paragraph from the section on Risk Factors:

We may incur significant costs resulting from product liability claims

We are subject to significant liability should use or consumption of our products cause injury, illness or death. Although we carry product liability insurance, there can be no assurance that our insurance will be adequate to protect us against product liability claims or that insurance coverage will continue to be available on reasonable terms. A product liability claim, even one without merit or for which we have substantial coverage, could result in significant legal defense costs, thereby increasing our expenses and lowering our earnings. Such a claim, whether or not proven to be valid, could have a material adverse effect on our product branding and goodwill, resulting in reduced market acceptance of our products. This in turn could materially adversely affect our results of operations and financial condition.

CAC ¶ 35. Appellants alleged that these statements were materially false and misleading because Appellees “failed to disclose that a lawsuit alleging that Zicam caused anosmia had already been filed and, given the findings of the researchers at the University of Colorado it was highly likely that additional suits would be filed in the future.” *Id.*

Matrixx issued a press release on January 7, 2004, in which it “upwardly revised its guidance for fiscal year 2003. The Company expects total 2003 revenues to grow by greater than 80 percent compared to 2002 and fully diluted earnings per share to be in the range of \$0.33 to \$0.38.” CAC¶ 37. Matrixx reported that “[t]he increase in the guidance for 2003 reflects a much greater incidence of colds than previously anticipated.” *Id.*

*4 On January 30, 2004, an article in the Dow Jones Newswires reported that the FDA was “looking into complaints that an over-the-counter common-cold medicine manufactured by a unit of Matrixx Initiatives Inc. (MTXX) may be causing some users to lose their sense of smell.” The article stated that “[t]he FDA's interest follows at least three lawsuits filed by individuals against Matrixx and Zicam LLC, a wholly-owned subsidiary, by users of Zicam Cold Remedy.”

Appellants alleged that Matrixx's stock declined after this report, “falling from \$13.55 per share on January 30, 2004 to \$11.97 per share on February 2, 2004.” CAC ¶ 41.

On February 2, 2004, Matrixx issued a press release, “respond[ing] to the Dow Jones ‘In The Money report: FDA Looks Into Complaints About Zicam,’ by Carol S. Remond, alleging that the FDA is investigating consumer complaints regarding intranasal zinc gluconate-induced loss of smell.” Matrixx 2/2/2004 press release. The press release stated:

Matrixx Initiatives, Inc., the manufacturer of Zicam(R) Cold Remedy, is not aware of an FDA inquiry into the safety of our intranasal zinc gluconate products....

All Zicam products are manufactured and marketed according to FDA guidelines for homeopathic medicine. Our primary concern is the health and safety of our customers and the distribution of factual information about our products. Matrixx believes statements alleging that intranasal Zicam products cause anosmia (loss of smell) are completely unfounded and misleading.

In no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function (sense of smell). Rather, the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established in two double-blind, placebo-controlled, randomized clinical trials. In fact, in neither study were there any reports of anosmia related to the use of this compound. The overall incidence of adverse events associated with zinc gluconate was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo

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subsets.

A multitude of environmental and biologic influences are known to affect the sense of smell. Chief among them is the common cold. As a result, the population most likely to use cold remedy products is already at increased risk of developing anosmia. Other common causes of olfactory dysfunction include age, nasal and sinus infections, [head trauma](#), anatomical obstructions, and environmental irritants.

The circumstances surrounding the development of Ms. Remond's column are extremely suspect. The article appeared online in public financial message boards almost immediately following its availability through the Dow Jones 'In The Money' subscription-only service. At least one of these message board postings was made by a registered username frequently used by Floyd Schneider, a defendant currently being sued for defamation by Matrixx Initiatives. From at least August 2001 to the present, Schneider has posted false and defamatory statements about Matrixx on various Internet message boards using a variety of anonymous aliases. It has come to our attention that Schneider has also attempted to interfere with Matrixx' business by contacting our retail customers.

*5 Ms. Remond's article appears on today's Dow Jones Newswire-the very day that Matrixx Initiatives is deposing Schneider. We believe that the timing of this article was manipulated by Schneider to interrupt the deposition process. We know that Ms. Remond and Schneider were in close communication during the development of Ms. Remond's article and even discussed the disclosure statement detailing the basis for our suit against Schneider, which has not yet been made public. Therefore, it is particularly troubling that Ms. Remond neglected to mention the defamation action or that Schneider was one of her chief sources of information. We consider her failure to mention these facts to be a significant omission in fair and balanced reporting.

Matrixx Initiatives would like to underscore that we intend to vigorously pursue those individuals involved in any effort to improperly discredit the company and its products. Furthermore, we strongly urge Dow Jones to open its own investigation to determine whether Dow Jones' credibility

was undermined by the use of copyrighted material in an attempt to do further harm to the value and reputation of Matrixx Initiatives and its products.

Matrixx 2/2/2004 press release. Appellants alleged that Matrixx's "vigorous, but baseless, denials had their intended effect: the stock price rose, closing at \$13.40 per share on February 3, 2004." CAC ¶ 41.

On February 6, 2004, the television show *Good Morning America* did a report on Matrixx's zinc gluconate products and anosmia. Reporter John Ferrugia reported that Jafek had treated " 'more than a dozen patients' " and that four lawsuits had been filed, and others were " 'being prepared.' " CAC ¶ 42. Appellants alleged that, "[i]n response to the *Good Morning America* segment ..., the price of Matrixx common stock plummeted, falling from \$13.05 per share on February 5, 2004, to close at \$9.94 per share on February 6-a one-day drop of 23.8% on unusually heavy trading volume." CAC ¶ 43.

On February 6, 2004, Matrixx issued another press release, describing the reports linking anosmia with zinc gluconate intranasal gels as "completely unfounded and misleading." Matrixx 2/6/2004 press release. Matrixx "assure[d] our consumers that Zicam Cold Remedy intranasal zinc gluconate products are manufactured and marketed according to Food and Drug Administration guidelines for homeopathic medicine." *Id.* Matrixx further asserted as follows:

In no clinical trial of intranasal zinc gluconate gel products has there been a single report of lost or diminished olfactory function (sense of smell). Rather, the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established in two double-blind, placebo-controlled, randomized clinical trials. In fact, in neither study were there any reports of anosmia related to the use of this compound. The overall incidence of adverse events associated with zinc gluconate was extremely low, with no statistically significant difference between the adverse event rates for the treated and placebo subsets.

*6 A multitude of environmental and biologic influences are known to affect the sense of smell. Chief among them is the common cold. As a result, the population most likely to use cold remedy products

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is already at increased risk of developing anosmia.
 ...

A few researchers have attempted to link nasal products containing zinc to the onset of anosmia. However, this hypothesis is based on data from polio studies conducted in the 1930s using a concentrated zinc sulfate solution. Current nasal products, such as Zicam Cold Remedy, contain zinc gluconate, which is an entirely different compound.

Matrixx 2/6/2004 press release.

On February 19, 2004, Appellees filed a Form 8-K with the SEC, in which Matrixx stated that it had “convened a two-day meeting of physicians and scientists to review current information on smell disorders.” CAC ¶ 45. The form stated that the meeting was in response to the September 20, 2003, presentation to the American Rhinologic Society. The form further stated that, “[i]n the opinion of the panel, there is insufficient scientific evidence at this time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell.”

On March 4, 2004, Ferrugia, the reporter on the *Good Morning America* segment, reported on TheDenverChannel.com that Matrixx “now admit[ted] that they don't know if their nasal gel could cause loss of smell.” CAC¶ 47. The article stated that “[t]he stunning information came after a 7NEWS investigation found that some consumers who have used Zicam report the loss of smell.” *Id.* The article reported that Matrixx initially “told us its studies showed the product [was] safe,” but that it would begin studies to determine if the product could cause the loss of smell. *Id.* (alteration in original). The article further provided as follows:

Doctors at the University of Colorado Taste and Smell Clinic have an increasing number of patients who say they lost their sense of smell after using Zicam intranasal gel, which contains zinc gluconate. Dr. Bruce Jafek has been documenting the cases from around the country, and there have been several lawsuits in at least five states. All along, Matrixx Initiatives, the maker of Zicam, said the product was safe. But now it admits there are no studies dealing with the issue. In a filing to the Securities and Exchange Commission on issues affecting stockholders, Matrixx now discloses:

“There is insufficient evidence at this time to determine if zinc gluconate, when used as recommended, affects a person's ability to smell.” What's more, after our initial investigation, dozens of consumers have filed complaints with the Food and Drug Administration. In response, the company formed a medical advisory panel in February. It says it will now conduct: “... animal and human studies to further characterize these post-marketing complaints.” Study findings are expected to be available in 12 months. “It seems to me that those studies should have been done before they put the product on the market,” said Jafek.

*7 *Id.*

On March 19, 2004, Matrixx filed its Form 10-K with the SEC, stating that “numerous suits alleging that its Zicam product(s) caused anosmia had been filed.” CAC ¶ 48. “As of December 31, 2003, suits involving three users of the Zicam® Cold Remedy nasal gel products had been filed in various federal and state courts.” *Id.* Appellants stated that, “[a]ccording to Matrixx's own SEC filings, from late 2003 through October 2004 Matrixx has been sued by approximately 284 individuals in 19 different lawsuits alleging that Zicam caused damage to their sense of smell,” and included in the complaint a table detailing the lawsuits. CAC ¶ 49. The table included suits filed on October 14, 2003, December 8, 2003, December 18, 2003, and January 23, 2004, as well as numerous suits following the close of the class period.

Appellants alleged that the financial information contained in Matrixx's Form 10-Q filed on November 12, 2003, was false and misleading and violated SEC rules and the Generally Accepted Accounting Principles (“GAAP”) promulgated by the Financial Accounting Standards Board (“FASB”). Appellants asserted that, at the time Matrixx filed the Form 10-Q,

Matrixx should have disclosed, if not provided a reserve for, a potential contingency that had arisen related to safety issues concerning its products. During the Class Period, Matrixx did not disclose that several lawsuits had been filed against the Company, including one prior to the start of the Class Period, alleging that the Company's zinc gluconate-based products had caused plaintiffs to suffer from anosmia and that anecdotal evidence had

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surfaced questioning the safety of the Company's mainstay cold medication. The failure to disclose these known contingencies violated GAAP.

CAC ¶ 55. Appellants listed the FASB rules violated by Matrixx's Form 10-Q and asserted that "the undisclosed adverse information concealed by defendants during the Class Period is the type of information which, because of SEC regulations, ... is expected by investors ... to be disclosed and is known by corporate officials ... to be the type of information which is expected to be and must be disclosed." CAC ¶¶ 56-57.

Appellants alleged that, "[a]s a result of defendants' materially false and misleading statements and failure to disclose adverse information regarding Zicam, Matrixx securities traded at artificially inflated prices during the Class Period." CAC ¶ 58. Appellants also alleged that, "[d]uring the Class Period, defendants materially misled the investing public, thereby inflating the price of Matrixx common stock, by publicly issuing false and misleading statements and omitting to disclose material adverse facts regarding Zicam, necessary to make defendants' statements, as set forth herein not false and misleading." CAC ¶ 59.

In the section of the complaint entitled "Additional Scienter Allegations," Appellants alleged as follows:

*8 [D]efendants acted with scienter in that defendants knew that the public statements or documents issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, defendants, by virtue of their receipt of information reflecting the true facts regarding Matrixx, their control over, and/or receipt and/or modification of the Company's alleged materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Matrixx, participated in the fraudulent scheme alleged herein.

Defendants were aware since at least September of 2003, that numerous users of their Zicam product

had experienced a rare condition known as anosmia or loss of smell. Findings of post treatment anosmia were reported by Dr. Bruce Jafek, Miriam R. Linschoten and Bruce W. Morrow of the University of Colorado School of Medicine, Department of Otolaryngology at a medical conference in September of 2003. At the time, Dr. Jafek had reported 10 cases of anosmia after Zicam use. As of April of 2004, Dr. Jafek had evaluated over 100 such cases. On September 12, 2003, over one month before the start of the Class Period, Matrixx informed Dr. Jafek that "as a legal matter" he did "not have their permission to use their company name or product trademarks" in the poster reporting Dr. Jafek's research. In order to avoid threatened legal action from the Company, Dr. Jafek deleted any reference to Zicam or Matrixx from the poster which he used to present his research at a medical conference.^{FN4}

CAC ¶¶ 63-64.

Appellees filed a motion to strike any allegations that concerned user complaints and lawsuits that occurred after the close of the class period. The district court denied the motion in part and granted it in part. The court reasoned that the relevant inquiry was not whether there was a link between Zicam and anosmia, but whether Appellees knew that their statements were false at the time they were made. The court therefore denied the motion to strike as to the complaints and lawsuits that were filed because those allegations were relevant to Appellees' knowledge of user complaints. However, the court granted the motion to strike as to Jafek's ultimate conclusions, which were published after the close of the class period.

The district court then dismissed the complaint without prejudice, reasoning, that the allegations of user complaints were not material because they were not statistically significant. The court also found that Appellants had failed sufficiently to allege scienter.

The court further stated that any amendment would be futile "[a]bsent allegations Defendants *knew* there was a definitive and statistically significant link between Zicam and anosmia *during the Class Period* that was sufficiently serious and frequent to affect future earnings." "The court therefore granted the motion to dismiss and dismissed the complaint without prejudice. The court then entered judgment, dismissing the complaint and the action without preju-

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dice.^{FNS} Appellants timely appealed.

STANDARD OF REVIEW

*9 [1] The district court's dismissal for failure to state a claim is reviewed de novo. Zucco Partners, LLC v. Digimarc Corp., 552 F.3d 981, 989 (9th Cir.2009). We accept the plaintiffs' allegations as true and construe them in the light most favorable to the plaintiffs. *Id.* Dismissal is "inappropriate unless the plaintiffs' complaint fails to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)).

DISCUSSION

[2][3] "Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), in combination with SEC Rule **10b-5**, prohibits 'any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.'" Rubke v. Capitol Bancorp Ltd., 551 F.3d 1156, 1164 (9th Cir.2009) (quoting 17 C.F.R. § 240.10b-5(c)). In order adequately to allege a violation of Rule **10b-5**, "a plaintiff must [allege] (1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss.'" *Id.* (quoting In re Daou Sys., Inc., 411 F.3d 1006, 1014 (9th Cir.2005)). The district court dismissed the complaint on the grounds that Appellants failed adequately to allege the first two elements; therefore, we address only those two elements.

I. Materiality

[4][5] Appellants contend that Appellees' failure to disclose information regarding the possible link between Zicam and anosmia constituted the omission of a material fact. "An omitted fact is material if there is a substantial likelihood that a reasonable shareholder would consider it important in deciding how to vote." TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449, 96 S.Ct. 2126, 48 L.Ed.2d 757 (1976).

[6] " 'Questions of materiality ... involv[e] assessments peculiarly within the province of the trier of fact.' " SEC v. Talbot, 530 F.3d 1085, 1097 (9th

Cir.2008) (quoting Arrington v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 651 F.2d 615, 619 (9th Cir.1981)) (alterations in original). Thus, "the ultimate issue of materiality [is] appropriately resolved 'as a matter of law' " only where the omissions are " 'so obviously important to an investor, that reasonable minds cannot differ on the question of materiality.' " TSC, 426 U.S. at 450 (quoting Johns Hopkins Univ. v. Hutton, 422 F.2d 1124, 1129 (4th Cir.1970)).

The district court summarized the "allegations of links between Zicam and anosmia for which Defendants had knowledge" as follows: "a phone conversation between a Matrixx vice-president and University of Colorado researcher discussing one anosmia complaint, a 1999 study recognizing a possible link, and a University of Colorado study citing 11 cases of anosmia in Zicam users." ^{FNS} District Ct. Order at 11. The court then found that Appellants had failed adequately to allege materiality because the number of complaints of which Appellees were aware was not "statistically significant." The court relied on the statistical significance standard used by the Second Circuit in In re Carter-Wallace, Inc. Securities Litigation, 150 F.3d 153, 157 (2d Cir.1998), and In re Carter-Wallace, Inc. Securities Litigation, 220 F.3d 36 (2d Cir.2000). We conclude, however, that the district court erred in relying on the statistical significance standard to conclude that Appellants failed adequately to allege materiality.

*10 [7] The Supreme Court has rejected the adoption of a bright-line rule to determine materiality because " '[t]he determination [of materiality] requires delicate assessments of the inferences a 'reasonable shareholder' would draw from a given set of facts and the significance of those inferences to him.' " Basic Inc. v. Levinson, 485 U.S. 224, 236, 108 S.Ct. 978, 99 L.Ed.2d 194 (1988) (quoting TSC, 426 U.S. at 450) (second alteration in original). Instead, courts should engage in a "fact-specific inquiry" in assessing materiality. *Id.* at 240. Thus, "[d]etermining materiality in securities fraud cases 'should ordinarily be left to the trier of fact.'" SEC v. Phan, 500 F.3d 895, (9th Cir.2007) (quoting In re Apple Computer Sec. Litig., 886 F.2d 1109, 1113 (9th Cir.1989)); see also No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp., 320 F.3d 920, 934-35 (9th Cir.2003) (declining to adopt a bright-line rule to determine materiality, engaging in the fact-specific inquiry required by *Basic*, and finding

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that the plaintiffs had sufficiently pleaded materiality).

In relying on the statistical significance standard to determine materiality, the district court made a decision that should have been left to the trier of fact. Instead, we agree with the approach of the court in *In re Pfizer Inc. Securities Litigation*, 584 F.Supp.2d 621 (S.D.N.Y.2008), where the United States District Court for the Southern District of New York rejected the defendant pharmaceutical company's argument that the plaintiffs failed to plead materiality, which was based on the contention that three studies revealing adverse effects of the company's drug were not statistically significant. The court reasoned that it "cannot determine as a matter of law whether such links were statistically insignificant because statistical significance is a question of fact." *Id.* at 635-36.

Thus, we are to engage in the fact-specific inquiry required by *Basic*. In doing so, we must take the allegations in the complaint as true and construe them in the light most favorable to Appellants and determine whether the complaint "fails to state a claim to relief that is plausible on its face." *Zucco*, 552 F.3d at 989 (internal quotation marks omitted). The following allegations in the CAC go to the question of whether the information regarding the possible link between Zicam and anosmia was information that a reasonable investor would have considered significant:

- In December 1999, Hirsch called Matrixx's customer service line and reported one patient who had developed anosmia after Zicam use and mentioned studies regarding intranasal application of zinc.
- In September 2002, Clarot called Linschoten because one of her patients had complained to Matrixx about Zicam and anosmia. Clarot told Linschoten that Matrixx had received similar complaints from other customers since 1999, and Linschoten told Clarot about studies linking zinc sulfate to loss of smell.
- *11 • On September 20, 2002, Linschoten sent Clarot an email with abstracts on the link between zinc sulfate and the loss of smell.
- In September 2003, Jafek presented findings about ten or eleven patients who suffered anosmia fol-

lowing Zicam use. Matrixx, through Clarot, stopped Jafek from using Matrixx's and Zicam's [names](#) in the presentation.

- On October 14, 2003, two plaintiffs filed suit against Matrixx in the United States District Court for the Western District of Michigan, alleging that Zicam caused anosmia.
- On December 8, 2003, a plaintiff filed suit against Matrixx in Los Angeles Superior Court regarding Zicam and anosmia.
- On December 18, 2003, another suit regarding Zicam and anosmia was filed against Matrixx in Alabama state court and removed to federal court.
- On January 23, 2004, five plaintiffs filed a consolidated suit against Matrixx in the Superior Court of Maricopa County, Arizona regarding Zicam and anosmia. An additional 261 plaintiffs later joined this action, after the close of the class period.
- By April 2004, Jafek "had evaluated over 100 cases of anosmia following Zicam use," and Linschoten had seen 65 cases, although the time period of these allegations is not clear.

We believe that the foregoing allegations are sufficient to meet the pleading requirement under the PSLRA, which requires that:

the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information or belief, the complaint shall state with particularity all facts on which that belief is formed.

[15 U.S.C. § 78u-4\(b\)\(1\)](#). The allegations in the CAC are sufficient to meet that standard and, as well, to "nudge[][Appellants'] claims across the line from conceivable to plausible." *Twombly*, 550 U.S. at 570. Appellants have sufficiently alleged materiality, and the district court's finding to the contrary is reversed.

II. Scienter

[\[8\]\[9\]\[10\]](#) In order to plead scienter, the PSLRA requires the complaint to "state with particularity facts

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giving rise to a strong inference that the defendant acted with the required state of mind.” [15 U.S.C. § 78u-4\(b\)\(2\)](#). The plaintiff “must allege that ... the defendant had an intention ‘to deceive, manipulate, or defraud.’” “*Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1065-66 (9th Cir.2008) (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193, 96 S.Ct. 1375, 47 L.Ed.2d 668 (1976)). “[I]n determining whether the pleaded facts give rise to a ‘strong’ inference of scienter, the court must take into account plausible opposing inferences.” *Tellabs, Inc. v. Ma-kor Issues & Rights, Ltd.*, 551 U.S. 308, 310, 127 S.Ct. 2499, 168 L.Ed.2d 179 (2007). The complaint will survive a motion to dismiss “only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.” *Id.* at 324. This does not mean that a plaintiff must “plead more than she would be required to prove at trial.” *Id.* at 311. Rather, “[a] plaintiff alleging fraud under § 10(b) action ... must plead facts rendering an inference of scienter *at least as likely as* any plausible opposing inference.” *Id.*

*12 [\[11\]\[12\]\[13\]](#) To establish scienter, “a complaint must ‘allege that the defendants made false or misleading statements either intentionally or with deliberate recklessness.’” “*Zucco*, 552 F.3d at 991 (quoting *Daou*, 411 F.3d at 1015). We must first “determine whether any of the plaintiff’s allegations, standing alone, are sufficient to create a strong inference of scienter.” *Id.* at 992. If not, we are to “conduct a ‘holistic’ review of the same allegations to determine whether the insufficient allegations combine to create a strong inference of intentional conduct or deliberate recklessness.” *Id.* Recklessness is defined as

a highly unreasonable omission, involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.

In re Silicon Graphics Inc. Sec. Litig., 183 F.3d 970, 976 (9th Cir.1999) (quoting *Hollinger v. Titan Capital Corp.*, 914 F.2d 1564, 1569 (9th Cir.1990) (en banc)).

The district court here concluded that the CAC failed

to allege the requisite scienter because it “fails to allege any motive or state of mind with relation to the alleged omissions.” In order adequately to allege scienter, Appellants rely on their allegations that Appellees knew about the problems with Zicam but chose not to reveal them. Appellants also argue that the importance of Zicam to Matrixx’s business supports the inference that Appellees intentionally withheld information of the link between Zicam and anosmia. Appellants also point to the revelations following the close of the class period that, contrary to their statements during the class period, Matrixx actually did not know if Zicam caused anosmia and decided to conduct studies after they had already vouched for the safety of Zicam.

Matrixx’s first allegedly misleading statement was its October 22, 2003, press release, announcing the 163% net sales increase, attributed to Zicam, and stating that the Zicam brand was “poised for growth.” The second statement was the conference call on October 23, 2003, again attributing the company’s positive results to Zicam and projecting further growth. By the time of the press release and the conference call, Hirsch had called the customer service line regarding one patient, Clarot had spoken with Linschoten regarding customer complaints, Jafek had presented his report of eleven patients, and the first lawsuit against Matrixx had been filed. Appellees accordingly were aware of at least fourteen complaints regarding Zicam and anosmia at the time they made these statements. In addition, Appellants alleged that Clarot told Linschoten in the September 2002 phone call that “Matrixx had received customer complaints of loss of smell as early as 1999.” Appellants then alleged that the November 12, 2003, Form 10-Q was misleading because it spoke of the risk of product liability actions against the company without revealing that a lawsuit already had been filed.^{FN7}

*13 In *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982 (9th Cir.2008), the defendants argued that a passage in the company’s SEC filings regarding backlog work alerted reasonable investors to the risk that the company might not get paid for work that had actually been stopped. We rejected the argument, stating that “[t]he passage ... speaks entirely of as-yet-unrealized risks and contingencies. Nothing alerts the reader that some of these risks may already have come to fruition, and that what the company refers to as backlog includes work that is substantially delayed

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and at serious risk of being cancelled altogether.” *Id.* at 986. We therefore disagreed with the district court's finding that the statements were not misleading, reasoning that, “once defendants chose to tout the company's backlog, they were bound to do so in a manner that wouldn't mislead investors as to what that backlog consisted of.” *Id.* at 987; cf. *In re Elan Corp. Sec. Litig.*, 543 F.Supp.2d 187, 208 (S.D.N.Y.2008) (“By choosing to speak about the safety of [their drug], Defendants assumed a duty to disclose material information regarding adverse events.”). After addressing scienter and loss causation, we reversed the district court's dismissal of the complaint. *Berson*, 527 F.3d at 987-90.

Similar to *Berson*, the passage in the Form 10-Q speaks about the risks of product liability claims in the abstract, with no indication that the risk “may already have come to fruition.” *Id.* at 986. At the time that Appellees filed the Form 10-Q, the CAC alleges facts sufficient for a jury to find that Clarot was aware of the potential anosmia problem. Moreover, the inference that high-level executives such as Johnson, Hemelt, and Clarot would know that the company was being sued in a product liability action is sufficiently strong to survive a motion to dismiss.

In response to the January 30, 2004, article in the Dow Jones Newswires that the FDA was investigating complaints of anosmia linked to Zicam, Matrixx issued a press release on February 2, 2004. By the time of this press release, three more lawsuits regarding anosmia had been filed against Matrixx. This press release cites the two double-blind studies regarding the “safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold,” but, again, the press release did not say whether Matrixx studied the intranasal use of zinc gluconate for safety, as opposed to efficacy. The press release also states that “statements alleging that intranasal Zicam products cause anosmia ... are completely unfounded and misleading,” and then devotes three paragraphs to discrediting the author of the article and urging Dow Jones to investigate the author.

By the time of the February 2, 2004 press release, a strong inference can be drawn that Appellees knew that the statements alleging a link between Zicam and anosmia were not “completely unfounded and misleading.” Appellees allegedly knew about the presentation by Jafek to the American Rhinologic Society,

Clarot's conversation with Linschoten, and several lawsuits alleging that Zicam caused anosmia. In addition, Matrixx's statements in the press release, that Zicam's safety was “well established” by their trials, conflict with the allegations that Clarot told Linschoten in September 2002 that Matrixx had not conducted any studies and asked her to participate in studies. The references in the press release to clinical trials establishing Zicam's safety also conflict with the March 4, 2004, news report that Matrixx did not know if Zicam could cause anosmia and formed a medical advisory panel to conduct studies.

*14 Matrixx's February 6, 2004, press release, following the *Good Morning America* segment regarding Jafek's findings, repeated the statements that the safety of zinc gluconate to treat cold symptoms had been established in clinical trials, stated that the common cold affects the sense of smell, and stated that the studies linking zinc to anosmia were conducted in the 1930s using a different zinc compound. Matrixx 2/6/2004 press release.

Appellants have not alleged that Appellees engaged in unusual or suspicious stock sales at the same time that they were attempting to downplay the reports of anosmia. See *Silicon Graphics*, 183 F.3d at 986 (stating that “unusual or suspicious stock sales by corporate insiders may constitute circumstantial evidence of scienter”) (internal quotation marks omitted). The Supreme Court has stated, however, that, “[w]hile it is true that motive can be a relevant consideration, and personal financial gain may weigh heavily in favor of a scienter inference, we agree with the Seventh Circuit that the absence of a motive allegation is not fatal.” *Tellabs*, 551 U.S. at 324.

On a holistic review of the CAC, the following picture is alleged. Matrixx received some customer complaints about Zicam and anosmia from 1999 to 2002. In 2002, Clarot was sufficiently concerned that he called Linschoten about one of her patients who had complained and then called to ask if she would participate in studies. In September 2003, Matrixx knew that Jafek and his colleagues were presenting findings about ten or eleven patients who developed anosmia after Zicam use and did not allow Jafek to use Matrixx's or Zicam's name in the presentation. In October 2003, Matrixx touted the potential for growth and profitability of Zicam in a press release and an earnings conference call. A lawsuit alleging

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anosmia in one Zicam user was filed in October 2003. In November 2003, Matrixx filed a Form 10-Q, but did not disclose the lawsuit in the section entitled “Risk Factors.”

More lawsuits were filed in December 2003 and January 2004.

On February 2, 2004, Matrixx issued a press release responding to the January 30, 2004, Dow Jones report that the FDA was investigating Zicam and anosmia. This press release called the report “completely unfounded and misleading” and asserted that clinical trials had established the safety of zinc gluconate. On February 6, 2004, *Good Morning America* reported on the possible link between Zicam and anosmia, and Matrixx issued another press release asserting that zinc gluconate's safety was well established in clinical trials, even though it was subsequently reported that Matrixx had not conducted such studies. In a February 19, 2004, filing with the SEC, Matrixx stated that it had convened a panel of physicians and scientists to review the information and asserted that there was insufficient evidence to determine whether zinc gluconate affected the sense of smell. On March 4, 2004, a news article reported that Matrixx would begin studies to determine if Zicam caused anosmia.^{FN8}

*15 [14] Viewing the CAC as a whole, the inference of scienter is “cogent and at least as compelling” as any “plausible non-culpable explanation []” for Appellees’ conduct. *Tellabs*, 551 U.S. at 324. Withholding reports of adverse effects of and lawsuits concerning the product responsible for the company's remarkable sales increase is “an extreme departure from the standards of ordinary care” and “presents a danger of misleading buyers or sellers.” *Silicon Graphics*, 183 F.3d at 976. We therefore conclude that the inference that Appellees withheld the information intentionally or with deliberate recklessness is at least as compelling as the inference that Appellees withheld the information innocently.

CONCLUSION

The district court's reliance on the statistical significance standard to conclude that Appellants failed to establish materiality is inconsistent with the Supreme Court's rejection of bright-line rules and its emphasis on having materiality determined by the trier of fact.

Viewing the CAC in the light most favorable to Appellants, we conclude that Appellants have sufficiently pled materiality to survive dismissal. Similarly, the inference that Appellees withheld the information regarding Zicam and anosmia intentionally or with deliberate recklessness is at least as compelling as any plausible nonculpable explanation. For the foregoing reasons, the judgment of the district court is **REVERSED** and the case **REMANDED** for further proceedings consistent with this opinion.

REVERSED and REMANDED.

FN1. On June 16, 2009, the Food and Drug Administration (“FDA”) issued a warning letter to Matrixx, setting forth the FDA's conclusion that several Zicam Cold Remedy products “may pose a serious risk to consumers who use them.” [http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm166909 .htm](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm166909.htm) (visited July 19, 2009; information moved to <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm166931.htm>). The FDA stated that it had received “more than 130 reports of anosmia, (loss of sense of smell, which in some cases can be long-lasting or permanent), associated with use of these products.” *Id.*

FN2. The following allegations are taken from the Consolidated Amended Complaint (“CAC”). In reviewing the district court's dismissal for failure to state a claim, we accept the plaintiffs' allegations as true and construe them in the light most favorable to the plaintiffs. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 989 (9th Cir.2009). As such, the allegations are hereafter stated as fact.

FN3. A lawsuit was filed against Matrixx and Zicam on October 14, 2003, in the United States District Court for the Western District of Michigan, alleging that Zicam caused anosmia. Matrixx was served on October 23, 2003, the day of the earnings conference call. *Christensen v. Matrixx Initiatives, Inc.*, No. 03-cv-0146, Docket No. 3.

FN4. We do not disturb the district court's

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order granting, in part, Appellees' motion to strike portions of the CAC related to research published after the close of the class period.

[FN5.](#) Although the judgment dismisses the action without prejudice, it is “final for purposes of [\[28 U.S.C.\] § 1291](#) [because] it (1) is a full adjudication of the issues, and (2) clearly evidences the judge's intention that it be the court's final act in the matter.” *Elliott v. White Mountain Apache Tribal Court*, 566 F.3d 845, 846 (9th Cir.2009).

[FN6.](#) The district court also reasoned that “Matrixx conducted a double-blind study regarding Zicam and not a single case of anosmia was reported.” This was presumably a reference to Matrixx's February 2, 2004, press release, which states that “the safety and efficacy of zinc gluconate for the treatment of symptoms related to the common cold have been well established in two double-blind, placebo-controlled, randomized clinical trials.” The press release, however, does not state that any tests established that the application of zinc gluconate to the nose is safe. In fact, as reported by Ferrugia on March 4, 2004, Matrixx allegedly subsequently admitted that “ ‘they don't know if their nasal gel could cause loss of smell,’ “ and that they would “begin ... testing to determine whether its zinc compound could be harmful when sprayed in the nose.” Moreover, the complaint alleged that Clarot told Linschoten in September 2002 that Matrixx had not conducted any studies and asked her to participate in studies.

[FN7.](#) As Matrixx later admitted, up to and including the class period, Matrixx had conducted no studies on the safety of Zicam regarding any link to anosmia.

[FN8.](#) We do not address Appellants' allegations that Appellees violated GAAP and FASB principles in the November 12, 2003, Form 10-Q. “Violations of GAAP standards can ... provide evidence of scienter,” but the violations must be described with sufficient particularity. [Daou](#), 411 F.3d at 1016.

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